

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401-7671q.

Dated: September 5, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95-22723 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 81

[WI56-01-7019b; FRL-5289-4]

Designation of Areas for Air Quality Planning Purposes; Wisconsin

AGENCY: Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: In this action USEPA proposes to remove all total suspended particulate (TSP) area designations in the State of Wisconsin. This action was prompted by the Wisconsin Department of Natural Resources' (WDNR) request to redesignate all areas in the State from TSP nonattainment to attainment. In the final rules section of this **Federal Register**, USEPA is approving the State's request as a direct final rule without prior proposal, because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this proposed rule. If USEPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The USEPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed action must be received by October 13, 1995.

ADDRESSES: Written comments should be sent to: Carlton T. Nash, Chief, Regulation Development Section, Air Toxics and Radiation Branch (AT-18J), USEPA Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604-3590.

FOR FURTHER INFORMATION CONTACT: Christos Panos, Regulation Development Section, Air Toxics and Radiation Branch (AT-18J), USEPA Region 5, 77

West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-8328.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**. Copies of the request and the USEPA's analysis are available for inspection at the following address: (It is recommended that you telephone Christos Panos at (312) 353-8328 before visiting the Region 5 Office.)

United States Environmental Protection Agency, Region 5, Air and Radiation Division, Air Toxics and Radiation Branch, 77 West Jackson Boulevard, Chicago, Illinois 60604-3590.

Authority: 42 U.S.C. 7401-7671(q).

Dated: August 17, 1995.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 95-22621 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 180

[PP 4E4419/P626; FRL-4970-8]

RIN 2070-AC

Avermectin B₁ and its Delta-8,9 Isomer

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish time-limited tolerances for the combined residues of the insecticide avermectin B₁ and its delta-8,9-isomer in or on the raw agricultural commodities dried hops and cattle fat. The proposed regulation to establish maximum permissible levels for residues of the insecticide was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4). The time-limited tolerances for dried hops and cattle fat would expire on April 30, 1996.

DATES: Comments, identified by the document control number [PP 4E4419/P626], must be received on or before October 13, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Comments and data may also be submitted to OPP by sending electronic mail (e-mail) to:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 4E4419/P626]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the "SUPPLEMENTAL INFORMATION" section of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information." CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8783; e-mail: jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 4E4419 to EPA on behalf of the Idaho, Oregon, and Washington Hop Commissions, and the Hop Growers of America. This petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.449 by establishing time-limited tolerances for the combined residues of the insecticide avermectin B₁ [a mixture of avermectins containing greater than or equal to 80 percent avermectin B_{1a} (5-O-demethyl avermectin A_{1a}) and less than or equal to 20 percent avermectin B_{1b} (5-O-demethyl-25-de(1-methylpropyl)-25-(1-

methylethyl) avermectin A_{1a})] and its delta-8,9-isomer in or on the raw agricultural commodities dried hops at 0.5 part per million (ppm) and cattle fat at 0.015 ppm.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. A 1-year feeding study with dogs fed diets containing 0.25, 0.50, or 1.0 milligram (mg)/kilogram (kg)/day with a no-observed-effect level (NOEL) of 0.25 mg/kg/day. A high incidence of mydriasis (excessive dilation of the pupil of the eye) was observed in male and female dogs at the 0.50-mg/kg/day dose level.

2. A 2-year chronic toxicity/carcinogenicity study with rats fed diets containing 0, 0.75, 1.5, or 2.0 mg/kg/day with a systemic NOEL of 1.5 mg/kg/day. Tremors were observed in male and female rats fed diets containing 2.0 mg/kg/day. No carcinogenic effects were observed under the conditions of the study.

3. A chronic toxicity/carcinogenicity study in mice fed diets containing 0, 2.0, 4.0, or 8.0 mg/kg/day for 94 weeks with a systemic NOEL of 4 mg/kg/day based on increased mortality, dermatitis, and extramedullary hematopoiesis in the spleen of males, and body weight loss in females at the 8.0 mg/kg/day dose level.

4. A two-generation reproduction study in rats fed diets containing 0, 0.06, 0.12, or 0.40 mg/kg/day with a NOEL of 0.12 mg/kg/day. The lowest-observed-effect level (LOEL) was established at 0.40 mg/kg/day based on increased retinal folds in weanlings, increased dead pups at birth, decreased viability indices, decreased lactation indices, and decreased pup body weights.

5. A developmental toxicity study with rats given gavage doses of 0, 0.4, 0.8, or 1.6 mg/kg/day with no developmental toxicity observed under the conditions of the study.

6. A developmental toxicity study with mice given gavage doses at 0, 0.1, 0.2, 0.4, or 0.8 mg/kg/day. The LOEL for developmental toxicity (cleft palate) was established at 0.4 mg/kg/day.

7. A developmental toxicity study with rabbits given gavage doses with NOEL's for developmental and maternal toxicity at 1.0 mg/kg/day. The LOEL for developmental toxicity was established at 2.0 mg/kg/day based on cleft palate, clubbed foot, and delayed ossification.

8. Avermectin B₁ tested negative for mutagenic effects in the Ames assay, V-79 mammalian cell assay, structural chromosomal aberration assay (*in vitro*

in Chinese hamster ovary cells), and *in vivo* bone marrow cytogenic study in male mice. Avermectin B₁ produced an increase in single strand DNA breaks in a rat *in vitro* hepatocyte mutagenicity study. However, no mutagenic effects were observed when the assay was carried out *in vivo* at 10.6 mg/kg.

Toxicity studies reviewed for the delta-8,9-isomer of avermectin B₁ include:

9. A developmental toxicity study in rats given gavage doses of 0, 0.25, 0.50, and 1.0 mg/kg/day with no developmental toxicity observed under the conditions of the study.

10. A mouse developmental toxicity study with a NOEL of 0.06 mg/kg/day based on developmental toxicity (cleft palate) at the 0.10 mg/kg/day dose level.

11. A one-generation reproduction study with rats fed diets containing 0, 0.06, 0.12, or 0.40 mg/kg/day with a NOEL for reproductive effects at 0.40 mg/kg/day. There were no reproductive effects observed under the conditions of the study.

12. An Ames mutagenicity study was negative in the presence of S-9 activation.

Dietary risk assessments for avermectin indicate that there is minimal risk from established tolerances and the proposed tolerances for dried hops and cattle fat. Dietary risk assessments were conducted using the Reference Dose (RfD) to assess chronic exposure and risk and the Margin of Exposure (MOE) for acute toxicity.

The RfD is calculated at 0.0004 mg/kg/day, based on a NOEL of 0.12 mg/kg/day of body weight/day from the two-generation reproduction study in the rat and an uncertainty factor of 300. The anticipated residue contribution (ARC) from existing tolerances and the proposed tolerances for dried hops and cattle fat utilizes 6 percent of the RfD for the general population and 21 percent of the RfD for nonnursing infants (less than 1-year old).

The MOE is a measure of how closely the high-end acute dietary exposure comes to the NOEL from the toxicity endpoint of concern. For avermectin the MOE was calculated as a ratio of the NOEL (0.06 mg/kg/day) from the mouse developmental toxicity study to dietary exposure, as estimated for the population subgroup at greatest risk (females of child-bearing age). The MOE for females of childbearing age is greater than 100 for high-end exposure. Acute dietary MOE's of of less than 100 are generally of concern to EPA.

The nature of the residue in or on hops is adequately understood. The enforcement method, which was developed by the registrant, Merck

Research Laboratories, has been validated by an independent laboratory. The enforcement method will be submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume II (PAM II), when EPA's Analytical Chemistry Laboratory has successfully completed its own validation of the enforcement method. The analytical method is being made available, in the interim, to anyone with an interest in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202 (703)-305-5937.

Any secondary residues will be covered by existing tolerances for meat, meat byproducts, and milk and the proposed tolerance for cattle fat at 0.015 ppm. The established tolerances for meat, meat byproducts, and milk will expire on April 30, 1996, which coincides with conditional registrations for use of avermectin on cotton and citrus. (See the **Federal Registers** of August 3, 1994 (59 FR 39505) and September 30, 1994 (59 FR 49825), for additional information regarding the conditional registrations for cotton and citrus.) The proposed tolerance for cattle fat will expire on April 30, 1996, which also coincides with the expiration date for time-limited tolerances for meat, meat byproducts, and milk. EPA intends to make a decision on the registrations for cotton and citrus prior to April 30, 1996. If full registration is issued, the time-limited restrictions will be removed from the avermectin tolerances for meat, meat byproducts, cattle fat, and milk.

EPA is establishing the tolerance for dried hops with an expiration date of April 30, 1996, to allow IR-4 time to submit additional residue data in support of a permanent tolerance for dried hops, and to allow EPA additional time to evaluate the enforcement method for dried hops. A permanent tolerance for dried hops must also await establishment of permanent tolerances for meat, meat byproducts, cattle fat, and milk.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is

proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 4E4359/P626]. Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

A record has been established for this rulemaking under docket number [PP 4E4419/P626] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having

an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment,

public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 30, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.449, by amending paragraph (a) in the table therein by adding and alphabetically inserting listings for cattle fat and dried hops and by amending paragraph (b) by revising the introductory text, to read as follows:

§ 180.449 Avermectin B₁ and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration date
Cattle, fat	0.015	Do.
* * *	* * *	* * *
Hops, dried	0.5	Do.
* * *	* * *	* * *

(b) A tolerance is established for the combined residues of the insecticide avermectin B₁ [a mixture of avermectins containing greater than or equal to 80 percent avermectin B_{1a} (5-O-demethyl avermectin A_{1a}) and greater than or equal to 20 percent avermectin B_{1b} (5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a})] and its delta-8,9-isomer in or on the following commodities:

* * * * *

[FR Doc. 95-22619 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 721

[OPPTS-50601F; FRL-4926-1]

Cyclohexanecarbonitrile, 1,3,3-trimethyl-5-oxo-; Revocation of a Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke a significant new use rule (SNUR) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for cyclohexanecarbonitrile, 1,3,3-trimethyl-5-oxo- based on receipt of new data. The data indicate that for purposes of TSCA section 5, the substance will not present an unreasonable risk to human health.

DATES: Written comments must be received by October 13, 1995.

ADDRESSES: All comments must be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-G99, 401 M St., SW., Washington, DC 20460. Comments that are confidential must be clearly marked confidential business information (CBI). If CBI is claimed, an additional sanitized copy must also be submitted. Nonconfidential versions of comments on this proposed rule will be placed in the rulemaking record and will be available for public inspection. Comments should include the docket control number. The docket control number for the chemical substance in this SNUR is OPPTS-50601F. Unit III.